[redacted]® Wound Solution

MAR 3 1 2014

510 (k)

SECTION 2	510(k) SUMMARY
510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter	PuriCore Inc., 508 Lapp Road Malvern, PA 19355
Contact Person	Art Morse; Director of Quality Assurance and Regulatory Affairs; PuriCore Inc. 508 Lapp Road, Malvern, PA 19355 484 321 2728 (O), 484 321 2704 (F), 610 306 2870 (C)
Date Prepared	June 18th, 2013
Trade Names	Vashe® Wound Solution
Common Name	Wound Cleanser, Hypochlorous Acid Solution
Classification Name	Solution, Saline, Wound Dressing
Product Code	FRO (Dressing, Wound, Drug)
Predicate Devices	Predicates with substantially equivalent chemical composition, mechanical action, and labeling: NeutroPhase Skin and Wound Cleanser®; NovaBay Pharmaceuticals, Inc. K113820, August 8th, 2012; Vashe® Wound Therapy Solution; PuriCore Inc. K123072, February 14, 2013 Wound Wash Saline; Blairex Laboratories, Inc. K083355, December 29, 2008 ExSept Skin and Wound Cleanser; Alcavis HDC LLC, K111313, December 14, 2011
Product Description	Vashe® Wound Solution is a saline based wound cleanser that contains hypochlorous acid as a preservative that inhibits microbial contamination within the solution. Vashe® Wound Solution creates a moist environment and loosens contaminated exudate, slough and other foreign materials within the wound bed. As a result of mechanical action of solution moving across the wound bed, dirt, debris, and microorganisms are more readily removed. Moistening and cleansing a wound, such as by using Vashe Wound Solution, better allows for the natural healing process to take place. This device is presented as a prescription product that requires the physician to diagnose the disease state and prescribe the product. The device is offered in three sizes of bottles, 4.0oz, 8.5oz, and 16.0oz and in two packaging configurations: Configuration #1: A PET bottle with a laminated induction seal and a polypropylene flip-top-cap configuration enables the user to manually pour the solution directly onto a wound or wound dressing. Configuration #2: The device is also offered in a PET bottle and a polypropylene cap (with septum configuration that forms the primary seal). The septum cap enables easy access to the solution by a healthcare professional by means of a vented spike connector.
Intended Use	Under the supervision of healthcare professionals, Vashe Wound Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and / or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

Vashe® Wound Solution	510 (k)

Summary of Technological Characteristics Compared to the Primary Predicate Devices (K123072) (K113820) (K083355) (K111313)	Vashe® Wound Solution has the same or similar technical characteristics as Vashe• Wound Therapy Solution, K123072, and NeutroPhase® Skin and Wound Cleanser K113820, Wound Wash Saline®, Blairex Laboratories, Inc. K083355, December 29th, 2008; *ExSept Skin and Wound Cleanser, K111313, December 14th, 2011;* • The mechanism of cleaning is the same as the predicates; the mechanism of fluid moving across the wound aids in the physical removal of foreign objects, foreign debris and exudate from a wound; • The Intended Use Statement utilizes the same indications as previously cleared under these predicate devices; • The closure system for this product is substantially equivalent to the predicates as it is packaged in a bottle and a Polypropylene cap (with a laminated induction seal or septum seal).
Substantial Equivalence - Effectiveness	Vashe® Wound Solution utilizes the same fundamental scientific technology as the predicate device (K123072); Non-Clinical equivalency testing was conducted for Shelf Life and Evaluated for Chemical Stability (See Section 6);
Substantial Equivalence – Safety	Biocompatibility studies proved that the product is equivalent to the predicate products as it was determine safe under the worst case scenario of the highest specified concentration of available free chlorine and the lowest specified pH. Additional in-vitro biocompatibility studies were conducted on keratinocytes and fibroblasts at the upper specification for available free chlorine concentration and at the lowest pH specification.
Conclusion:	Non clinical product testing has proven that Vashe Wound Solution is substantially equivalent to the predicate devices as the product has been subjected to in-vivo and in-vitro biocompatibility testing per ISO-10993-1 standards and Preservative Effectiveness testing to USP <51>. These results demonstrate that the product is as safe, as effective, and performs as well as or better than the legally marketed devices identified as the reference predicate devices listed above and in the Substantial Equivalence section (5).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 31, 2014

PuriCore Incorporated
Mr. Art Morse
Director of Quality Assurance and Regulatory Affairs
508 Lapp Road
Malvern, Pennsylvania 19355

Re: K131848
Trade/Device Name: Vashe Wound Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 28, 2014
Received: March 4, 2014

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131848

Device Name
Vashe Wound Solution

Indications for Use *(Describe)*
Under the supervision of healthcare professionals, Vashe Wound Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and / or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites; and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S